REMARKS

In the accompanying amendment, claim 1 is amended and claims 12 and 13 have been added. The amendments to the claims are supported by the original filed specification, claims, and drawings. Thus, it is respectfully submitted that the amendments to the claims do not add new matter.

Claim Rejections under 35 USC §103

Claims 1, 5, 8, and 11 stand rejected under 35 USC 103(a) as being unpatentable over Ebert et al. (WO 95/24172) (pub. Sept. 14 1995) in view of Visser et al. (WO 98/56325) (pub. Dec. 17, 1998). Applicant traverses.

Claim 1 recites the limitation: the proximal layer being further characterized in that its permeability to the irritating substance or component of the composition to be administered to the human or animal is less than the permeability of the human or animal skin, as the case may be, to such irritating substance or component, thereby to reduce irritation of the human or animal skin.

Ebert attempts to solve the problem of skin irritation through the use of anti-irritants (see p 13). However, Ebert does not disclose that the proximal layer has a permeability to the irritating substance that is less that the permeability of human or animal skin to the irritating substance.

Likewise, Visser teaches at page 19 teaches the use of a local anti-irritant such as glycerin to combat the problem of skin irritation. However, Visser does not disclose that the proximal layer has a permeability to the irritating substance that is less that the permeability of human or animal skin to the irritating substance.

Stated differently, both Ebert and Visser teach away from having the permeability of the proximal layer to the drug being administered to be less than the permeability of human or animal skin to reduce irritation of the human or animal skin.

In fact both Ebert and Visser provide no basis for the idea that the problem of skin irritation can be solved by reducing the permeability of the proximal layer to the drug being administered relative to the permeability of human or animal skin to the drug.

The Examiner argues that one skilled in the art would combine the teachings of Landauer (WO/13885) to modify the teachings of Ebert and Visser thereby to prevent irritant build up at the proximal layer. The motivation to do so, according to the Examiner, is that Visser was aware that DMF is a skin irritant. Applicant, however, argues that both Visser and Ebert taught the use of glycerin as a solution to the problem of skin irritation. Thus, one of ordinary skill in the art would not be aware that skin irritation was still a problem to be solved given the teachings of Ebert and Visser. Given the lack of a perceived skin irritation problem, one of ordinary skill in the art would therefore not be motivated to combine Landauer with the teachings of Ebert and Visser. At any event, Landauer teaches the use of vitamin E to reduce skin irritation. Thus, Landauer was also not aware that skin irritation could be reduced by making the permeability of the proximal layer to the drug to be less than the permeability of human or animal skin to the drug. Futher. Landuaer states as a design constraint the desirability of making the desorption of the drug through the membrane to be the same or very close to the absorption tempo of the skin. Landauer does not state the basis of this design constraint. Be that as it may, Landauer does not teach or suggest making the permeability of the proximal layer to the drug to be less than the permeability of human or animal skin to the drug.

Based on the foregoing, it is respectfully submitted that claim 1 is not obvious in view of Ebert and Visser or Ebert, Visser, and Landauer.

Claims 1, 4, 7, and 9 stand rejected under 35 USC 103(a) as being unpatentable in view of Ebert, Visser, and Landuaer. Applicant traverses this rejection on the basis of the above arguments.

Claims 10 stands rejected under 35 USC 103(a) as being unpatentable in view of Ebert, Visser, Landuaer, and Reed (US 5,827,530). Applicant traverses this rejection on the basis of the above arguments.

With regard to new claims 12 and 13, these claims include the following limitations:

A method for administering a drug transdermally, comprising:

depositing the drug in a cavity formed between a distal layer and a proximal layer of a transdermal patch; wherein the distal layer is impermeable to the drug, and the proximal layer is permeable to the drug and adapted to be in contact with human or animal skin; and

reducing irritation of the human skin or animal due to components of the drug by preventing build up of the drug between the proximal layer and the human skin or animal skin.

As argued above Ebert, Visser and Landauer all teach the addition on a non-irritant to the drug composition, but fail to teach or suggest reducing irritation by preventing drug build up at the proximal layer.

Accordingly, it is respectfully submitted that claims 12-13 are not anticipated or rendered obvious in view of Ebert, Visser, and Landauer.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (650) 7965417 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 503437.

Respectfully submitted,

Quinton Van Rooyen et al.

By their Representatives,
Hahn and Moodley LLP

Customer Number 52418

Date 10/4/2010 By /Vani Moodley/
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